SOLICITATION, OFFER AND AWARD	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE 1 OF PAGES 57

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO.
	DHHS-ORDC-V&B-05-08	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	03/17/2006	

7. ISSUED BY CODE

Department of Health and Human Services
OS/OPHEP/ORDC
200 Independence Ave. SW, Room 636G
Washington, DC 20201

8. ADDRESS OFFER TO *(If other than Item 7)*

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and 12 copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8 , or if handcarried, in the depository located in Block 7 until 3:00pm *(Hour)* local time 05/02/2006 *(Date)*

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE NUMBER EXT:	C. E-MAIL ADDRESS
	Darrick A. Early	(202) 205-5668	Darrick.early@hhs.gov

11. TABLE OF CONTENTS

(x)	SEC.	DESCRIPTION	PAGE(S)	(x)	SEC.	DESCRIPTION	PAGE(S)
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OFFER *(Must be fully completed by offeror)*

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 180 calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS %	20 CALENDAR DAYS %	30 CALENDAR DAYS %	CALENDAR DAYS %

14. ACKNOWLEDGMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN *(Type or Print)*

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM

24. ADMINISTERED BY *(If other than Item 7)* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

U.S. Department of Health and Human Services
Office of Public Health Emergency Preparedness
Office of Research and Development Coordination
RFP-DHHS-ORDC-V&B-05-08
Advanced Development of Antigen Sparing Pandemic Influenza Vaccines

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.fedbizopps.gov/

2. SECTION A – SOLICITATION/CONTRACT FORM – OMB No. 0990-0115

NOTE: The issuance of this solicitation does not commit the government to an award.

3. Issue Date:	**4.** Due Date:	**5. Small Bus. Set-Aside:** [ ]Yes [x] No **8(a) Set-Aside:** [ ]Yes [x] No **NAICS:** 325414 (See Part IV, Section L.)
See SF-33	See SF-33	

6. Proposal Delivery Information	**7. Number of Awards:**	**8. Technical Proposal Page Limits:**
See SF-33	[ ] Only 1 Award [x] Multiple Awards	See Section J and L

9. Issued By:	**10.** [X] **ORDC reserves the right to make awards without discussion.**	
See SF-33	**11. Options:** **[X] No** **[ ] Yes**	**12. Period of Performance:** 3-5 years beginning on/about September 30, 2006

13. Primary Point of Contact:	**14. Secondary Point of Contact:**	**15. Collect Calls will not be accepted. Facsimile submissions are not acceptable.**
Name: Darrick A. Early **Phone:** 202-205-5668 **Fax:** 202-205-6092 **E-Mail: darrick.early@hhs.gov**	**Name:** David K. Beck **Phone:** 202-205-5639 Fax: 202-205-6092 **E-Mail: david.beck@hhs.gov**	

16. Reserved

17. DELIVERY ADDRESS INFORMATION

18. Hand Delivery or Overnight Service:	**19. Packaging of Proposals:**
Darrick A. Early Contract Specialist HHS/OPHEP/ORDC 200 Independence Avenue, Room 636G Washington, D.C. 20201	See Section J for proposals packaging instructions

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 18, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This project from the Department of Health and Human Services (HHS) through the Office of Research and Development Coordination (ORDC) within the Office of Public Health Emergency Preparedness (OPHEP) will provide incremental multi-year, cost-reimbursable contracts to organizations such as biopharmaceutical companies, medical delivery device companies, or vaccine manufacturers for the development of antigen sparing approaches and products used as or with pandemic influenza vaccines leading towards U.S.-licensure from U.S.-based manufacturing sites for products not readily available at the onset of an influenza pandemic. The approach may include adjuvants, immune cytokines, immunostimulants, other biologicals, or medical delivery devices that when used with pre-pandemic and pandemic influenza vaccines afford enhanced immunogenicity (fewer immunizations) and/or an antigen sparing effects (less antigen utilization). Depending on the Offeror's stage of product development, the scope of activities for which the Offeror may request funds may include the production of products or devices for clinical investigation including consistency lots, clinical evaluation including comparability studies and clinical sample analysis of vaccination results for safety, immunogenicity, and efficacy needed for licensure, scale up manufacturing and process development and validation, product manufacturing equipment, and manufacturing concept facility design and validation. The objective of this project is to stretch the domestic influenza vaccine supply in the event of an influenza pandemic.

B.2. HHSAR 352.232-74 Estimated Cost and Fixed Fee -- Incrementally Funded Contract (Apr 1984)

(a) It is estimated that the total cost to the Government for full performance of this contract will be $_____, of which the sum of $_____ represents the estimated reimbursable costs and $_____ represents the fixed-fee.

(b) Total funds currently available for payment and allotted to this contract are $_____, of which $_____ represents the estimated reimbursable costs and $_____ represents the fixed-fee. For further provisions on funding, see the Limitation of Funds clause.

(c) It is estimated that the amount currently allotted will cover performance through (date)_____.

(d) The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

B3. Cancellation Ceiling

(a) This clause does not apply when the contract is fully funded.

(b) The total funding in B.2(b) includes an amount that covers the cancellation charge described in FAR 52.217-2, Cancellation Under Multi-year Contracts. The cancellation charge shall not exceed _____ (insert dollar amount or express as a percentage of total funding under B.2 (b).

B.4. CONTRACT LINE ITEM NUMBERS (CLINS)

ITEM	SUPPLIES / SERVICES	QTY/UNIT	EST. COST	FIXED FEE	TOTAL EST. CPFF
0001	**Product Development Plan** (milestone 1)	**1 Job**	**$**	**$**	**$**
0002	**Non-Clinical Development, Clinical Development, and Regulatory Licensure Plans** (milestone 2)	**1 Job**	**$**	**$**	**$**
0003	**Production Plan** (milestone 3)	**1 Job**	**$**	**$**	**$**

0004	**Contractor Defined Milestones** (milestone 4)	**1 Job**	**$**	**$**	**$**
0005	**Technical Progress Reports and Executive Summary**	**12 reports per year**	**$**	**$**	**$**
0006	**Final Report**	**1 report**	**$**	**$**	**$**

SECTION C - DESCRIPTION/SPECIFICATIONS

C.1. BACKGROUND/STATEMENT OF WORK

Background

Introduction and Rationale

Preparedness for public health threats is a major goal of the U.S. Department of Health and Human Services (DHHS). An influenza pandemic has a greater potential to cause large numbers of deaths and illnesses over a short time period than virtually any other natural health threat. A pandemic occurs when there is an antigenic shift in an influenza A virus and transmission of a new strain to which most or all of the world's population is susceptible. Three pandemics occurred during the 20th century, the most severe of which, in 1918, caused over 500,000 U.S. deaths and more than 20 million deaths worldwide. Within the scientific community, it is generally believed that the occurrence of another influenza pandemic is inevitable. Recent outbreaks of human disease caused by avian H5, H9, and H7 influenza strains in Asia, Europe, and North America highlight the potential of new strains to be introduced into the population. Estimates for the next pandemic, extrapolating from those of the 20th century, range from about 100,000 to over 2 million deaths in the U.S. alone.

Influenza vaccines are considered a primary means to decrease the mortality and morbidity associated with the next pandemic. HHS is pursuing multiple strategies to close the gap between pandemic influenza vaccine supply and the stated HHS goal of 600 million doses of pandemic vaccine within six (6) months of the declaration of an influenza pandemic. However, current U.S. influenza vaccine production capacity falls far short of expected pandemic response needs. Vaccines produced outside of the United States likely will be used to protect the population in its country of origin and become unavailable to the U.S., despite preexisting contractual arrangements and national treaties. This shortfall in domestic surge capacity for pandemic influenza vaccines is exacerbated further for H5N1 vaccines, as results of recent clinical studies showed that two doses of H5N1 vaccine formulated at 90 µg HA alone/dose may be necessary for protection. Other studies with H5N1 vaccine formulated with alum adjuvant indicate that less HA antigen may be needed.

One strategy to increase domestic pandemic influenza vaccine surge capacity is to stretch the number of doses by enhancing immunogenicity, thereby decreasing the number of doses and/or amount of vaccine hemagglutinin antigen required in each dose to induce protective immunity. Another strategy is to enhance immunity such that only one vaccination is needed to elicit protective immunity. Potential “antigen-sparing” products may include adjuvants, immunostimulants, immune cytokines, or other biologicals formulated with or independent of influenza vaccine antigens, presentation of these biologicals by new methods, or administration of influenza vaccines or immune enhancing products by novel delivery methods or administration routes with medical devices.

Antigen-sparing strategies could potentially extend U.S. pandemic influenza vaccine supply several-fold, substantially improving the ability to protect the U.S. population rapidly in a pandemic and potentially leading to vaccine availability internationally for countries that have no domestic production. Strategies that can be implemented by influenza vaccine manufacturers worldwide rather than being tied to a specific manufacturer or product would be most advantageous. For an antigen sparing strategy to contribute to pandemic preparedness and response, that strategy must be effective in decreasing the amount of vaccine antigen required to induce a protective immune response; it must be licensed and available at the time of the pandemic; and it must be feasible to implement as in a mass vaccination program.

Purpose

The purpose of this solicitation is to support advanced stage development of enhanced immunity and/or antigen-sparing strategies for pandemic influenza vaccination leading toward submission of a U.S. licensure application and development of required industrial capacity to support implementation of the antigen sparing strategy with pandemic influenza vaccine at full production capacity at or before the onset of a pandemic. Incremental multi-year funding for cost-reimbursement contracts to organizations such as biopharmaceutical companies, medical delivery device companies, and/or vaccine manufacturers will be provided to support this effort. Ultimately these antigen-sparing influenza vaccines or products shall be produced at one or more Food and Drug Administration (FDA)-licensed manufacturing facilities and shall provide sufficient surge capacity to contribute substantially to U.S. and ideally global vaccine needs during an influenza pandemic.

Objectives

Using intellectual property to which the company has unencumbered and documented access and documents "freedom to operate," the successful Offeror shall accomplish the following objectives associated with advanced development of a pandemic influenza vaccine antigen-sparing technology:

a) Conduct preclinical and clinical testing to assess the safety, immunogenicity and efficacy, as required by the FDA of the antigen-sparing strategy, and to define the type and magnitude of the antigen sparing effect for monovalent influenza vaccine against novel influenza strains (i.e., H5N1 or other subtypes not currently circulating among people) that are considered to have pandemic potential. Monovalent vaccines against novel influenza strains may be manufactured by the Offeror or subcontractor at a facility in compliance with current Good Manufacturing Practices (cGMP) guidelines and current World Health Organization (WHO) biosafety guidelines for pandemic influenza vaccine manufacturing. (2005).

b) Develop a preclinical and clinical manufacturing and testing plan with the supportive regulatory development plan that will lead to submission of a licensure application. The Offerors should seek guidance from the FDA on the clinical development plan for their antigen-sparing products and should indicate in the proposal whether the clinical development plan reflects FDA's guidance.

c) Develop a plan to manufacture the antigen-sparing pandemic influenza vaccine or products in a licensed facility based in the U.S. or, for a product with long-term stability that is suitable for stockpiling at an FDA-licensed facility in the U.S. or at a foreign site with a capacity to support rapid stockpile purchases commensurate with U.S. pandemic influenza vaccine needs.

Activities that may be supported by this solicitation shall include product toxicology studies in animals, clinical lot manufacturing including consistency lots for usage as or with pandemic influenza vaccines, clinical evaluation studies of the antigen-sparing strategy for safety and immunogenicity, process and manufacturing scale up development, product lot release assay development and process validation; product-dedicated manufacturing equipment; facility concept design and facility validation. USG support shall not be provided for building a manufacturing facility or purchasing an existing facility.

Additional information

In addition, it is critical that offerors understand the following:

This advanced development contract is milestone-driven and funding is expected to occur in phases. Periodic assessments of progress will be conducted by DHHS. Continuation of effort on initial and subsequent milestones and associated funding will be based on contractor performance, timeliness and quality of deliverables, availability of other antigen sparing strategies and products deemed more advantageous to the USG, and consultations between the contractor, DHHS, and interagency working group members. In the event that more than one award is made, the government reserves the right to down-select at any time. This paragraph does not limit the Government's rights under contract clauses that include, but are not limited to, FAR 52.217-2, Cancellation Under Multi-year contracts, and 52.249-6, Termination (Cost-Reimbursement).

Statement of Work

Independently and not as an agent of the government, the contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities not otherwise provided by the government as needed to perform the work described below.

The proposal will include a Contractor Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget. The level of detail contained in the CWP and the corresponding Gantt chart will be sufficient to facilitate management and execution of the contract by the successful offeror.

Milestones

I. Milestone 1: Within three (3) months of contract award, the Contractor shall provide to the HHS for review and acceptance a milestone-driven **Product Development Plan** for development of antigen sparing pandemic influenza vaccine or related products. This plan shall include: a) pre-clinical studies, as needed, to support clinical testing; b) process development and scale up manufacturing of monovalent pandemic influenza vaccine product or use with this vaccine to novel influenza viruses; c) clinical and consistency lot manufacturing for FDA product licensure, d) general clinical development plan including development and validation of clinical sample assays (see Milestone 2); e) product lot release assay development and validation, and f) regulatory master plan for product licensure (see Milestone 2). Pandemic monovalent influenza vaccine used in these studies may be produced by the Offeror or a corporate partner.

II. Milestone 2: Within six (6) months of contract award, the Contractor shall submit to HHS for review and acceptance complete milestone-driven **Non-Clinical Development, Clinical Development ,and Regulatory Licensure Plans** to initiate vaccine and/or device development, pre-clinical studies, or clinical studies, as appropriate based on the current stage of development and as outlined in the development, testing, and manufacturing plan.

A A pre-clinical testing plan that is integrated with the clinical testing and manufacturing plans using the most current and available information including consultation with Center for Biologics Evaluation and Research (CBER) at FDA. If this stage of product development has been completed, then a detailed summary of the studies and results should be incorporated as an appendix in the preliminary results section of the technical proposal.

B. A clinical testing plan that is integrated with the pre-clinical testing and manufacturing plans using the most current and available information including consultation with FDA CBER. Clinical trials performed as a result of this solicitation shall include any of Phase I, Phase 2, and Phase 3 trials, as needed to achieve U.S. licensure. Trials should include children, adults, and the elderly, as needed, to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the schedule for each clinical trial should clearly indicate key outcomes, populations, study sites and collaborators, analytic strategy, sample size, timelines, and other key components. Studies should be done using monovalent influenza vaccine to a novel influenza strain with and without the product providing enhanced immunity and/or antigen-sparing effect. If one or more these stages of product development have been completed, then a detailed summary of the studies and results should be incorporated as an appendix in the preliminary results section of the technical proposal.

C. A regulatory plan that is integrated with all products and clinical testing and manufacturing activities using the most current and available information including consultation with FDA CBER.

III. Milestone 3: Within twelve (12) months of contract award, the Contractor shall provide the USG with one or more of the following, as appropriate for the antigen sparing product(s) being developed:

A. A P**roduction Plan** to produce at least 150 million doses of the monovalent antigen sparing pandemic influenza vaccine within a 6 month period.

B. If the antigen sparing strategy relies on a non-vaccine product that is not suitable for long term stockpiling,

the Contractor must provide a P**roduction Plan** to produce at least 150 million units within 6 months or requiring no more than 1-month lead time before the first units are produced of the product at a licensed or licensable U.S.-based facility.

C. If the antigen sparing strategy uses a delivery device that is suitable for long term stockpiling, the Contractor must provide a P**roduction Plan** to produce and make available to the U.S. Government first within a 6 month manufacturing period at a U.S.-licensed facility and at reasonable cost, a quantity commensurate with delivery of at least 150 million vaccine doses.

D. A P**roduction Plan** shall contain the concept architectural and mechanical engineering descriptions, drawings of functional areas, and flow diagrams of personnel, product, raw materials, and waste for the manufacturing facilities and ancillary product testing laboratories. Major product related equipment should be indicated in the description and drawings that would permit vaccine or product production for pandemic purposes as levels and timeframes indicated above.

The manufacturing facility and production processes shall be maintained in compliance with current Good Manufacturing Practices (cGMP) for all manufacturing operations and current Good Laboratory Practices (cGLP) for testing laboratories, as applicable. Ability to meet standards for Biosafety Level (BSL) 2 + and 3 as described in WHO biosafety guidelines for pandemic influenza vaccine manufacturing may be necessary, if the Contractor will be handling and testing highly pathogenic avian influenza viruses or derivatives to generate pandemic influenza vaccines.

IV. Milestone 4: **Contactor defined milestones.** The Contractor shall provide within 12 months a work breakdown structure including comprehensive and integrated timelines (Gantt chart) and major milestones to complete the remaining the scope of work as relevant given the stage of vaccine and/or device development and evaluation toward product licensure. The Contractor shall propose milestones at which time data will be presented summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential milestones may include FDA acceptance of an IND application, production of an investigational lot of vaccine and/or delivery system, validation of facilities, systems, and equipment, validation of QC lot release product methods, validation of manufacturing processes, stability study programs, consistency lot manufacturing, completion of a clinical trial and progress to a new phase of vaccine evaluation, submission of a licensure application, etc.

[END OF STATEMENT OF WORK]

Meetings and conferences:

The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Project Officer. Such meetings may include, but are not limited to, meetings of all Contractors and subcontractors to discuss clinical manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues,; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences with the Contractor and subcontractors with HHS officials will be held at times and dates to be determined to review technical and product development progress, except during clinical lot manufacturing when meetings shall be held on a weekly basis.

C.2. REPORTING REQUIREMENTS

In addition to those reports required by other terms of this contract, the Contractor(s) shall submit to the Contracting Officer and the Project Officer technical progress reports covering the work accomplished during each reporting period on a periodical basis as established by the Project Officer. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the following format:

I. Technical Progress Reports: On the fifteenth of each month for the previous calendar month or within fifteen days past the achievement of prescribed project milestones, the Contractor shall submit to the Project Officer and the Contracting Officer. The frequency of Technical Progress Reporting will be determined by the Contracting Officer and Project Officer during negotiations of the contract. The format and type of Technical Progress Report and Executive Summary will be provided by the Project Officer. Technical Progress Reports will include project timelines and milestones and summaries of product manufacturing, testing, and clinical evaluation. A Technical Progress Report will not be required for the period when the Final Report is due. The Contractor shall submit one copy of the Technical Progress Report electronically via e-mail. Any attachments to the e-mail report shall be submitted in Microsoft Word or Word Perfect, Microsoft Excel, Microsoft Project Manger, and/or Adobe Acrobat PDF files. Such reports shall include the following specific information:

   A. Title page containing Technical Progress Report, the contract number and title, the period of performance or milestone being reported, the contractor's name, address, and other contact information, the author(s), and the date of submission;
   B. Introduction/Background - An introduction covering the purpose and scope of the contract effort;
   C. Progress - The report shall detail, document, and summarize the results of work performed, test results, and milestones achieved during the period covered. Also to be included is a summary of work planned for the next reporting period;
   D. Issues - Issues resolved, new issues, and outstanding issues are enumerated with options and recommendations for resolution. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and, if project activity is delinquent, then what corrective steps are planned. Revised timelines are provided.
   E. Invoices – Summary of any invoices submitted during the reporting period.
   F. Action Items – Summary table of activities or tasks to be accomplished by a certain date and by whom.
   G. Distribution List – A list of persons receiving the Technical Progress report
   H. Attachments – Results on the project are provided as attachments

II. The Executive Summary, which shall accompany each Technical Progress Report, will be formatted in Microsoft Power Point presentations and include the following:

   A. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission;
   B. Project Progress presented as milestone events, test results, tasks, and other activities achieved during the reporting period as talking point bullets;
   C. Project Issues presented headings and each item as a talking point bullet.

III. Final Reports - By the expiration date of the contract, the Contractor shall submit a comprehensive Final Report that shall detail, document, and summarize the results of the entire contract work. The report shall explain comprehensively the results achieved. A draft Final Report will be submitted to the Project Officer for review and revision, then the original, four copies, and an electronic file containing the Final Report with revisions shall be submitted to the Project Officer for distribution to the Contracting Officer and the Program.

SECTION D--PACKAGING, MARKING AND SHIPPING

D.1. SHIPPING

I. Method of Delivery

Unless otherwise specified by the Contracting Officer or the Contracting Officer's representative, delivery of items, to be furnished to the government under this contract (including invoices), shall be made by first class mail.

II. Addressees – For all contract deliverables.

Project Officer
HHS/OPHEP/ORDC
200 Independence Avenue SW
Room 636 G
Washington, D.C. 20201

Contracting Officer
HHS/OPHEP/ORDC
200 Independence Avenue SW
Room 636 G
Washington, D.C. 20201

SECTION E--INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative will inspect and accept materials and services to be delivered under the contract. The contract will identify who will perform inspections and where the inspections will be performed. In addition, the following clause is incorporated by reference:

FAR Clause No.52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APR 1984)

SECTION F--DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The period of performance of this contract is from the date of contract award to _____months after contract award.

Delivery will be required F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEE'S PREMISES (APR 1984).

F.2. Technical Report Distribution

Item	Deliverable	Quantity	Due Date
1.	**Technical Progress Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1st Report due on/before _____; thereafter, due on/before the 15th of the month or milestone following each reporting period. Not due when Final is due.
2.	**Executive Summary**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	1st Report due on/before _____; thereafter, due on/before the 15th of the month following each anniversary date of the contract. Not due when Final is due.
3.	**Final Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Due on/before the completion date of the contract.

F.3. Contract Deliverables

Milestones	Deliverable	Quantity	Due Date
1.	**Product Development Plan** (milestone 1)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Three (3) months after contract award.
2.	**Non-Clinical Development, Clinical Development, and Regulatory Licensure Plans** (milestone 2)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Six (6) months after contract award.
3.	**Production Plan** (milestone 3)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Twelve (12) months after contract award.
4.	**Contractor Defined Milestones** (milestone 4)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	Within Twelve (12) months after contract award.
5.	**Technical Progress Reports and Executive Summary**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	See section C.2.Reporting requirements.
6.	**Final Report**	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – P.O.	See section C.2.Reporting requirements.

F.4. STOP WORK ORDER

The following clause is incorporated by reference:

FAR CLAUSE 52.242-15, STOP WORK ORDER (AUG 1989) with ALTERNATE I (APR 1984)

SECTION G.--CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

1) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract.

2) The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

3) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

G.2. PROJECT OFFICER

The Government's Project Officer(s) will be identified in the contract.

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

G.3. KEY PERSONNEL

Contractor personnel considered by the Government to be essential to contract performance will be identified here. The Contracting Officer must be notified prior to replacing any of these individuals on the contract.

G. 4. INVOICE SUBMISSION

Invoices will be submitted in accordance with "Invoice/Financing Request Instructions" attached to this contract. Addresses for submitting invoices will be included in the contract.

G. 5. CONTRACT FINANCIAL REPORT

Financial reports will be submitted to the address specified in Block 7 of face page of the contract. Normally, reports are due quarterly. Examples of the cost elements to be reported include the following:

Expenditure Category

1. Direct Labor
    a. Principal Investigator
    b. Co-Principal Investigator
2. Personnel - Other
3. Fringe Benefits
4. Materials/Supplies
5. Travel
6. Consultant Costs
7. Subcontract Costs

8. Other Direct Costs
9. Clinical Trials Costs
10. Indirect Cost
11. Fee
12. Total Cost

G. 6. INDIRECT COST RATES

Profit making organizations will negotiate provisional and/or final indirect cost rates with their cognizant Government Audit Agency.

G. 7. POST AWARD EVALUATION OF PAST PERFORMANCE

Interim and final evaluations of contractor performance shall be conducted on this contract in accordance with FAR 42.15. The final performance evaluation shall be completed at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement.

G.8. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this paragraph will include applicable provisions and incorporate the HHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990), which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

SECTION H--SPECIAL CONTRACT REQUIREMENTS

H. 1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Milestone 2 has been approved by DHHS, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying Internal Review Board (IRB) review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

H. 2. HUMAN MATERIALS

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under this contract will be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

H. 3. ANIMAL WELFARE ASSURANCE

The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

H. 4. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small, Small Disadvantaged and Women Owned Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8 entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "LIQUIDATED DAMAGES--SUBCONTRACTING PLAN."

b. Subcontracting Reports

As of October 28, 2005 the Electronic Subcontract Reporting System (eSRS) is available for use by all civilian agencies and their contractors at www.esrs.gov. The eSRS will eliminate both standard forms Subcontracting Reports for Individual Contracts (formerly SF 294) and Summary Subcontract Reports (formerly SF 295) paper submissions, and contractors will now submit all their reports electronically to a single, government wide system. The eSRS is the latest system under the umbrella of the Integrated Acquisition Environment (IAE).

All civilian agency contractors must now submit their Summary Subcontract Reports into the eSRS.

No contractors of any agency will be required to submit the Subcontracting Reports for Individual Contracts into the eSRS for fiscal year 2004.

No contractors of any agency will be required to submit mid-year reports for fiscal year 2005 (normally due April 30 for the period ended March 31st) into the eSRS. This exemption applies to both the Subcontracting Reports for Individual Contracts and the Summary Subcontract Reports.

Frequently Asked Questions and other information are available on the eSRS website at www.esrs.gov. If you have any further questions or comments, you may contact the SBA at eSRS@sba.gov or the IAE at integrated.acquistion@gsa.gov.

H. 5. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, confidentiality of Information (APR 1984): Data obtained from human subjects

H. 6. REVIEW AND APPROVAL

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without written approval in advance from the Government.

H. 7. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H. 8. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H. 9. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in DHHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov.

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, DC 20026

H. 10. ACKNOWLEDGMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 104-208 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

   This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity

   The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of Public Health Emergency Preparedness, Office of Research and Development Coordination whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

   "This project has been funded in whole or in part with Federal funds from the Office of Public Health Emergency Preparedness, Office of Research and Development Coordination, under Contract No. *[insert #]*"

C. Press Releases

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H. 11. NEEDLE EXCHANGE

Pursuant to Section 505 of Public Law 105-78, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

H. 12. PRESS RELEASES

Pursuant to Section 508 of Public Law 105-78, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money that: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

H. 13. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provisions of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H. 14. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice Regulations (cGMP) (21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing and packing of this therapeutic product.

If at any time during the life of the contract, the Offeror fails to comply with cGMP in the manufacturing, processing and packaging of this therapeutic product and such failure results in a material adverse effect on the safety, purity or potency of this therapeutic product (a material failure) as identified by CBER and CDER, the Offeror shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the Offeror fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H. 15. ANTI-LOBBYING PROVISIONS

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 10, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio,

television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or and State or Local legislature.

H. 16. POSSESSION, USE AND TRANSFER OF SELECTED BIOLOGICAL AGENTS OR TOXINS

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins: Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety); Agricultural Bioterrorism Protection Act of 2002, which consists of 7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins (relating to plant health or plant products); and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins (relating to human and animal health, animal health or animal products) - December 13, 2002

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using DHHS funds for research involving Select Agents. No DHHS funds can be used for research involving Select Agents if the final registration certificate is denied. For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the DHHS that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. In the technical proposal, the offeror must include details about the select agent and the quantity proposed to be used during contract performance. When requested by the contracting officer during negotiations, potential awardees must provide information addressing the following key elements for the foreign institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of DHHS grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. Toward this end, when requested during negotiations, potential awardees will be asked to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, foreign institutions must provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the resulting contract. If the proposed contract work will not involve Select Agents, the offeror must include a statement in their technical proposal that the proposed work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents. Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program.

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP. **OFFERORS ARE ENCOURAGED TO REVIEW THESE CLAUSES AND TO DISCUSS ANY QUESTIONS THEY MAY HAVE ABOUT THEM DURING NEGOTIATIONS. THE FULL TEXT OF THESE CLAUSES MAY BE ACCESSED ELECTRONICALLY AT THESE ADDRESSES:**
http://www.arnet.gov
http://www.dhhs.gov/oamp/dap/hhsar.html/

I.1. GENERAL CLAUSES

General Clauses for a Cost-Reimbursement Research and Development Contract

FAR	52.202-1	Jul 2004	Definitions
FAR	52.203-3	Apr 1984	Gratuities (Over $100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
FAR	52.203-12	Sep 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
FAR	52.204-7	Oct 2003	Central Contractor Registration
FAR	52.209-6	Jan 2005	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
FAR	52.215-15	Oct 2004	Pension Adjustments and Asset Reversions

FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.217-2	Oct 1997	Cancellation Under Multi-Year Contracts
FAR	52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
FAR	52.219-9	Jul 2005	Small Business Subcontracting Plan (Over $500,000)
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
FAR	52.225-1	Jun 2003	Buy American Act – Supplies
FAR	52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
FAR	52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
FAR	52.227-14	Jun 1987	Rights in Data – General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-	Jun	Interest (Over $100,000)

	17	1996	
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost (applies when contract is fully funded)
FAR	52.232-22	Apr 1984	Limitation of Funds (applies when contract is incrementally funded)
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over $100,000)
FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
FAR	52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
FAR	52.244-6	Feb 2006	Subcontracts for Commercial Items
FAR	52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons

HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Authorized substitutions and/or modifications of the General Clauses will be based on the type of contract and Contractor and will be determined during negotiations. The following clauses may be applicable and may be made a part of the resultant contract.

FAR Clause **52.232-20, Limitation of Cost**, is deleted in its entirety and FAR Clause **52.232-22, Limitation of Funds** (APRIL 1984) is substituted therefore. [Note: When this contract is fully funded, FAR Clause **52.232-22, Limitation of Funds** will no longer apply and FAR Clause **52.232-20, Limitation of Cost** will become applicable.]

I.3. ADDITIONAL CONTRACT CLAUSES

The following clause(s), as applicable, will be made part of the resultant contract. Please note that any contract resulting from this solicitation is not limited to the clauses listed below. These clauses represent some of the most commonly used. Any additional clauses deemed necessary by the Government will be discussed during negotiations.

52.204-8 Annual Representations and Certifications (Jan 2006).

ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2006)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 325414.

(2) The small business size standard is 500.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (c) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (c) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

[ ] (i) Paragraph (c) applies.

[ ] (ii) Paragraph (c) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are

incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR CLAUSE #	TITLE	DATE	CHANGE
_____	_____	____	_____

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of provision)

52.215-17 Waiver of Facilities Capital Cost of Money (October 1997)

52.243-2, Changes—Cost Reimbursement (August 1987)

I.4 Additional Contract Clauses of SECTION I – Added in full text

52.222-39 Notification of Employee Rights Concerning Payment of Union Dues or Fees.

Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2004)

(a) Definition. As used in this clause—
"United States" means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.
(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).
Notice to Employees
Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.
If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.
For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)
To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR Part 470, and orders of the Secretary of Labor.
(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR Part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR Part 470, which implements Executive Order 13201, or as are otherwise provided by law.
(e) The requirement to post the employee notice in paragraph (b) does not apply to—

(1) Contractors and subcontractors that employ fewer than 15 persons;
(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;
(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;
(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that—
(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or
(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.
(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall—
(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;
(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov; or
(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.
(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR Part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

I. 5. Department of Health and Human Services Acquisition Regulations (HHSAR)

(48 CFR Chapter 3) Clauses: Full text of these clauses can be found at
http://www.dhhs.gov/oamp/dap/hhsar.html/

352.223-70, Safety and Health (January 2001)

352.224-70, Confidentiality of Information (April 1984)

352.270-5, Key Personnel (April 1984)

352.270-8, Protection of Human Subjects (January 2001)
Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human Subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

352.270-9, Care of Live Vertebrate Animals (January 2001)

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

1. **PACKAGING AND DELIVERY OF PROPOSALS**

2. **HOW TO PREPARE AN ELECTRONIC PROPOSAL**

3. **PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: March 31, 2006]**

   [NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for the Program's coordination and review of proposals.]

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **Proposal Summary and Data Record**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours, proposed Subcontracts and all other items of costs (i.e., travel, materials and supplies, etc.)**
- **Offeror's Points of Contact**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Read all instructions on this page and in the RFP before mailing or submitting forms, proposals, or CDs.

Your proposal will have **two separate parts**.

- Business proposal
- Technical proposal

In addition, several other forms are required -- see the RFP and the table below for details.

You will submit your proposal in **two formats**: paper and CDs or USB Drives.

- The paper proposal with original signatures is the official, legally binding copy. There are no acceptable substitutes.
- The CD or USB memory stick versions of the proposal are for the benefit of ORDC. Electronic versions may or may not be used for review, at the discretion of ORDC.

As a potential offeror, you must routinely check the FedBizOpps for amendments because we do not notify you directly of changes.

Send your proposal to ORDC at the address below. If you have any questions, ask the primary or secondary ORDC contacts specified in the RFP.

Hand written proposals will not be accepted.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal. Proposals will not be returned to the offeoror.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	**File Size**
Technical Proposal	One (1) bound SIGNED ORIGINAL. Five (5) copies bound in three ring binders CDs or USB Drives	Limited to not-to-exceed 40 Pages	Unlimited
Technical Proposal Appendices All materials shall be available electronically (i.e. SOPs, Pertinent Manuals, Figures or Data, and Letters of Collaboration/Intent).	One (1) bound SIGNED ORIGINAL. Five (5) copies bound in three ring binders . CDs or USB Drives	This information is included in the total page limitation of 250 pages.	Unlimited
Business Proposal	One (1) bound SIGNED ORIGINAL. Five (5) bound copies. in three ring binders CDs or USB Drives	Limited to not-to-exceed 250 pages	Unlimited
Representations and Certifications	Provide representations and certifications electronically via the BPN website (www.bpn.gov/orca)	N/A	N/A

TECHNICAL PROPOSAL PAGE LIMITS INCLUDE: The technical approach to be used by the Offeror(s) in order to implement the requirements stated in the Statement of Work. **TOTAL PAGE COUNT DOES NOT INCLUDE**: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

COURIER DELIVERIES WILL BE TO THE FOLLOWING ADDRESS:

Attn: Contract Specialist
HHS/OPEHP/ORDC
200 Independence Ave., SW
Room 636 G
Washington, D.C. 20201
Phone: 202-205-5668

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in Box 18 of the RFP cover page and must be received on/before the closing date and time.

For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Documents must be converted to a .pdf searchable format.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Pages printed front-to-back will count as 2 pages.
- Pages may not be printed in column format.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: DHHS-ORDC-V&B-05-08
RFP Title: "Advanced Development of Antigen Sparing Pandemic Influenza Vaccines"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **March 31, 2006**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
HHS/OS/OPHEP/ORDC
200 Independence Avenue
Room 636 G
Washington, D.C. 20201
Attn: Darrick A. Early
RFP-HHS-ORDC-V&B-05-08
FAX# (202) 205-6092
Email: Darrick.Early@hhs.gov

TECHNICAL PROPOSAL COVER SHEET

IN RESPONSE TO RFP-DHHS-ORDC-V&B-05-08

TITLE: Advanced Development of Antigen Sparing Pandemic Influenza Vaccines

OFFEROR (Primary organization/institution):

Name and Address:

PRINCIPAL INVESTIGATOR:

OFFEROR PERSONNEL Name (Last, First, Initial) and Degree(s)*

SUBCONTRACTOR ORGANIZATIONS (If more than one, list each organization and its personnel separately):

Name and Address:

PRINCIPAL INVESTIGATOR:

SUBCONTRACTOR PERSONNEL Name (Last, First, Initial) and Degree(s)*

COLLABORATORS or CONSULTANTS:

Name [Last, First, Initial) Degree(s)] Organization

* List all co-investigators/key personnel

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR
AND DIRECT COSTS (Sample)

COST ELEMENT	Milestone 1 (Period Covered)	Milestone 2 (Period Covered)	Milestone 3 (Period Covered)	Milestone 4 (Period Covered)			Total
DIRECT LABOR:							
Labor Category	(Hours)	(Hours)	(Hours)	(Hours)			Total
(Title and Name– use additional pages as necessary)							
DIRECT LABOR COST:	$	$	$	$	$	$	$
MATERIAL COST:	$	$	$	$	$	$	$
TRAVEL COST:	$	$	$	$	$	$	$
CONSULTANTS:	$	$	$	$	$	$	$
SUBCONTRACTS:	$	$	$	$	$	$	$
CLINICAL TRIAL/PATIENT CARE COSTS:	$	$	$	$	$	$	$
EQUIPMENT	$	$	$	$	$	$	$
OTHER DIRECT COSTS	$	$	$	$	$	$	$
OTHER (Specify)	$	$	$	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$	$	$	$
TOTAL COST:	$	$	$	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$	$	$	$

Specific Instructions:

1. Do not include any individual salary information
2. Do not include any indirect cost or fee.
3. Do not submit the total amount of proposal.
4. Submit this information as a portion of the Technical Proposal.

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals***** in this proposal.

Professional's Name and Title/Position:

	Identifying Number	Agency	Total Effort Committed
1.			
2.			
3.			
4.			

*****If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*****.

Professional's Name and Title/Position:

	Identifying Number	Agency	Total Effort Committed
1.			
2.			
3.			
4.			

*****If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

	Name	Title/Position	Total Proposed Effort
1.			
2.			
3.			
4.			

OMB No. 0990-0263
Approved for use through 11/30/2008

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

licy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

titutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date _____
[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

NOTE: This Notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this RFP. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR 352.215-1.

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or [[Page 4256]] statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **PROPOSAL SUMMARY AND DATA RECORD**	RFP/CONTRACT NUMBER
PROJECT TITLE (Title or RFP or Contract Proposal)	
LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)
TYPE OF CONTRACT PROPOSED COST-REIMBURSEMENT FIXED PRICE COST-PLUS-FIXED-FEE OTHER	
ESTIMATED TIME REQUIRED TO COMPLETE PROJECT	
ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE
DOES THIS PROPOSAL INCLUDE A SUBCONTRACT YES NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)	

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS YES NO
Institution's General Assurance re: Human Subjects DATE APPROVED _____ PENDING
Institution's Review Board's Approval of this Proposal DATE APPROVED _____ PENDING
An example of the informed consent for this study is enclosed YES NO
A Clinical Protocol is enclosed YES NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE RFP (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

Provision of the Social Security Number is voluntary. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE)
AND LABOR HOURS

INSTRUCTIONS FOR USE OF THE FORMAT

Proposals submitted under this RFP will require cost analyses and or audits of each element of cost proposed. Offeror(s) will be asked to submit supporting documentation to verify the accuracy of all proposed costs. Supporting documents will be required for labor rates, equipment, subcontracts, consultant costs, clinical trials costs, and any other significant category. For further information concerning requirements for Cost or Pricing Data, see Item 24 under Section L.

1. Refer to Business Proposal Instructions, Section L of this solicitation. The Instructions contain the requirements for proper submission of cost/price data which must be adhered to.

2. This format has been prepared as a universal guideline for all solicitations issued by the OPHEP/ORDC. It may require amending to meet the specific requirements of this solicitation. For example, this solicitation may require the submission of cost/price data for three years listed on this form. (See Section L.1., General Information for the estimated duration of this project.) If this solicitation is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. This format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs, indirect costs and fee, if applicable. In addition, provide detailed calculations for all items. For example:

   a. For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years.

      Offeror's proposal should be stated in the same terms as will be used to account for and record the effort under a contract. If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. The attached format should be revised to accommodate direct labor proposed as a percentage of effort.

   b. For all materials, supplies, equipment (including binding bids for all equipment greater than $5,000), and other direct costs, list all unit prices, etc., to detail how the calculations were made.
   c. For all indirect costs, list the rates applied and the base the rate is applied to.
   d. For all travel, list the specifics for each trip.
   e. **For any subcontract proposed, submit a separate breakdown format. This shall include cost support, full breakdown of all cost related to subcontracts, and all other internal costs.**
   f. Justification for the need of some cost elements may be listed as an attachment, i.e., special equipment, above average consultant fees, etc.

4. If the Government has provided "uniform pricing assumptions" for this solicitation, the offeror must comply with and identify each item.

5. **It is requested that you use the ELECTRONIC SPREADSHEET that is provided below to prepare your business proposal in lieu of the hardcopy contained in this Attachment. It is in EXCEL format and has instructions for use and submission.**

   If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

   For security purposes, please include a hard copy of the completed spreadsheet and submit the electronic file with your proposal.

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS (Sample)

COST ELEMENT	Milestone 1 (Period Covered)	Milestone 2 (Period Covered)	Milestone 3 (Period Covered)	Milestone 4 (Period Covered)			Total
DIRECT LABOR:							
Labor Category Rate	(Hours)	(Hours)	(Hours)	(Hours)			Total
(Title and Name– use additional pages as necessary)							
DIRECT LABOR COST:	$	$	$	$	$	$	$
MATERIAL COST:	$	$	$	$	$	$	$
TRAVEL COST:	$	$	$	$	$	$	$
CONSULTANTS:	$	$	$	$	$	$	$
SUBCONTRACTS:	$	$	$	$	$	$	$
CLINICAL TRIAL/PATIENT CARE COSTS:	$	$	$	$	$	$	$
EQUIPMENT	$	$	$	$	$	$	$
OTHER DIRECT COSTS	$	$	$	$	$	$	$
OTHER (Specify)	$	$	$	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$	$	$	$
FRINGE BENEFIT COST: (if applicable) % of Direct Labor Cost	$	$	$	$	$	$	$
INDIRECT COST: % of Total Direct Cost	$	$	$	$	$	$	$
TOTAL COST:	$	$	$	$	$	$	$
FEE: % of Total Est. Cost	$	$	$	$	$	$	$
GRAND TOTAL ESTIMATED CPFF	$	$	$	$	$	$	$

***The above breakdown shall be used for each milestone in the Statement of Work, including any proposed offeror milestones (refer to milestone four (4) of the statement of work).**

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Name, Institutional Title and Address of Proposed Principal Investigator

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Subcontractor(s): Name, Institutional Title and Address of Proposed Principal Investigator

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*****Please use actual street address, not P.O. Box.

DISCLOSURE OF LOBBYING ACTIVITIES **Approved by OMB 0348-0046**

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action:	2. Status of Federal Action:	3. Report Type:
a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	a. bid/offer/application b. Initial award c. post-award	a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report_____

4. Name and Address of Reporting Entity:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime
☐ Prime ☐ Subawardee Tier_____, if known: Congressional District, if known:	Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	b. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ ☐ actual ☐ planned	13. Type of Payment (check all that apply): ☐ a. retainer ☐ b. one-time fee ☐ c. commission ☐ d. contingent fee ☐ e. deferred ☐ f. other; specify: _____
12. Form of Payment (check all that apply): ☐ a. cash ☐ b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached:
Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature:_____ Print Name:_____ Title:_____ Telephone No.:_____Date:_____
Federal Use Only	Authorized for Local Reproduction Standard Form—LLL

DISCLOSURE OF LOBBYING ACTIVITIES

CONTINUATION SHEET
Approved by OMB

0348-0046

Reporting Entity:_____ Page _____ of _____

Authorized for Local Reproduction
Standard Form--LLL-A

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing of attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

Federal Acquisition Circular (FAC 2001-26), published on December 20, 2004, implements the ***Online Representations and Certifications Application (ORCA)*** effective on January 1, 2005. The ORCA became a Federal mandate as published in the Federal Acquisition Circular 2001-26, FAR case 2002-024, and now requires the use of ORCA in Federal solicitations as a part of the proposal submission process.

ORCA is part of the Business Partner Network (BPN) which is a component of the Integrated Acquisition Environment (IAE) E-Gov initiative. It is a web-based system that centralizes and standardizes the collection, storage and viewing of many of the FAR required representations and certifications previously found in solicitations. With ORCA, you now have the ability to enter and maintain your representation and certification information, at your convenience, via the Internet at http://orca.bpn.gov. In addition, rather than receiving and reviewing paper submissions, government contracting officials can access ORCA and review your information online as a part of the proposal evaluation process. You will no longer be required to submit representations and certifications completed in ORCA with each offer.

The final rule requires offerors to: (a) provide representations and certifications electronically via the BPN website (www.bpn.gov/orca) thus reducing the administrative burden on vendors who have been submitting the same reps and certs repeatedly for various solicitations, (b) to maintain the representations and certifications at least annually so they stay current, (c) to make changes that affect only one solicitation by completing sections of specific provisions that are required by the FAR, included in the solicitation. This will result in a reduced paperwork burden for both offerors and contracting officers thus fulfilling one of the goals of IAE to re-use data as much as possible throughout the Federal procurement life cycle.

To comply with this requirement and to register in ORCA, you will need to have two items: an active Central Contractor Registration (CCR) record and a Marketing Partner Identification Number (MPIN) identified in that CCR record. Your DUNS number and MPIN act as your company's ID and password into ORCA. (Visit www.ccr.gov for more information on creating and entering your MPIN). The basic information provided in your CCR record is used to pre-populate a number of fields in ORCA. Vendors are reminded to protect their MPIN from unauthorized use. Once in ORCA you will be asked to review pertinent information pre-populated from CCR, provide a point of contact, and answer a questionnaire that contains up to 26 questions. The questionnaire is to help you gather information you need for the clauses. The questionnaire is not the official version. Be sure to read the provisions carefully.

The answers you provide are then automatically entered into the actual FAR provisions. You are required to review your information, as inserted, in context of the full-text provisions for accuracy; acknowledge three additional read-only provisions; and click a time/date stamp before final submission. You will need to review and/or update your ORCA record when necessary, but at least annually in order to maintain its active status. Detailed information regarding ORCA, how to submit your record, and whom to call for assistance can be found on ORCA's homepage at http://orca.bpn.gov under "Help." The ORCA site contains an ORCA Application Handbook and an ORCA Quick Reference Guide. To access them, simply click on the "Help" link at the top of the ORCA homepage.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLY WITH THE ABOVE REQUIREMENT.
(See FAR Clause 52.204-8 listed I.3.)

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation.

I. GENERAL INFORMATION

ITEM 1: **FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION, and its Alternate I** are applicable to this solicitation.

In accordance with HHSAR 352.215-1, paragraph (e) is substituted for subparagraph (e) of the provision at FAR 52.215-1.
(e)Restriction on disclosure and use of data.
(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads: Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.
The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).
(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:
"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."
(3) Offerors are cautioned that proposals submitted with restrictive legends or [[Page 4256]] statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

As prescribed in FAR 15.209(a)(1), the following paragraph (f)(4) is substituted for the paragraph (f)(4) of the basic provision:

(f)(4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposal have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

ITEM 2: **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, **SMALL BUSINESS PROGRAM REPRESENTATION,** FAR Clause 52.219-1.

(1) The NAICS Code is 325414.
(2) The small business size standard is 500 employees.

ITEM 3: **THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS.** However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

ITEM 4: TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one or more awards will be made from this solicitation and that the award(s) will be made on/about September 30, 2006.

It is anticipated that the award(s) from this solicitation will be a multiple-year, cost-reimbursement, completion type contract, with a period of performance of three (3) to five (5) years as agreed to during negotiations, and that incremental funding will be used.

ITEM 5. PRE-PROPOSAL CONFERENCE

A pre-proposal conference will be held with prospective offerors at HHS, Humphrey Building, 200 Independence Ave, SW, Washington, D.C. 20201 on or about **April 11, 2006**. The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any question which you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before March 31, 2006 at the address cited in Block 7 of the face page of this solicitation.

Your questions should be submitted to the primary point of contact specified in Block 13 of page 2 of the solicitation and the envelope should be marked, "Pre-proposal conference, RFP No. DHHS-ORDC-V&B-05-08." Letters containing questions for the pre-proposal conference can also be fax to 202-205-6092. A set of all questions and answers will be posted as an amendment to the RFP in the FedBizOpps.

Because of space limitations, each prospective offeror shall be limited to a total of 3 representatives. Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

ITEM 6: COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

ITEM 7: COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. **Communications with any Government official regarding this RFP is strictly prohibited and may disqualify your proposal for further consideration.**

ITEM 8: **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (*Complete address and contact information can be found on the SOLICITATION/OFFER and AWARD cover page, Block 13, of the RFP*) by obtaining written and dated acknowledgment of receipt.

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

ITEM 9: LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

ITEM 10: AUTHORIZED OFFICIAL AND SUBMISSION OF PROPOSAL

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled,

PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE
Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL
It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL
It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

ITEM 11: Alternate Proposals (May 1998)

The offeror may, at its discretion, submit alternate proposals or proposals that deviate from this solicitation's requirements; provided that the offeror also submits a proposal for performance of the work as specified in the statement of work. Alternate proposals may be considered if performance would be improved or not compromised, and if they are in the best interest of the Government. Alternate proposals, or deviations from any requirements of this RFP, must be clearly identified.

ITEM 12: Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

ITEM 13: **Potential Award Without Discussions,** The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

ITEM 14: **Small Business Subcontracting Plan,** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation. **A Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if your proposal is determined to be in the competitive range. Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal) http://www.hhs.gov/osdbu/forms.html**

The anticipated minimum subcontracting goals for this RFP are as follows:

- 23% for Small Business
- 5% for Small Disadvantaged Business
- 3% for Women-Owned Small Business
- 5% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% Service-Disabled Veteran-Owned Small Business.

ITEM 15: **Extent of Small Disadvantaged Business Participation** is applicable to this solicitation.

ITEM 16: **Past Performance Information** is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the **Business** proposal.

1. Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.
2. The Offeror shall provide a list of the last three (3) contracts completed during the past three years and all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts as required above for all key personnel:
   a. Name of Contracting Organization
   b. Contract Number
   c. Total Contract Value
   d. Description of Requirement
   e. Contract Officer's name and telephone number

ITEM 17: **Solicitation Provisions Incorporated by Reference:** The following provisions are applicable to this solicitation.

Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).

Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 18: Human Subjects, is applicable to this solicitation. See the Statement of Work and Section M.6 for additional information concerning human subjects.

ITEM 19: **Animal Welfare Assurance**

The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

Offerors must submit their plan on how they will comply with all requirements concerning the use of animals for experimentation and be in accordance with any requirements specified in the http://grants.nih.gov/grants/olaw/olaw.htm.

ITEM 20: **Manufacturing Capacity and Commitment to Produce Products Suitable for Stockpiling**

The offeror shall submit with technical proposal written evidence of a firm commitment by the Offeror that the Offeror will initiate the establishment of the necessary facilities for the manufacturing of antigen sparing products that can be maintained long term in a stockpile with sufficient capacity such that at least 150 million units could be purchased by the USG for a stockpile within a 6 month period after U.S. licensure.

ITEM 21: Technical Proposal Instructions

TECHNICAL PROPOSAL INSTRUCTIONS

General Comment: Offerors may identify tasks, among those described in this solicitation, for which they plan to utilize subcontractors. This approach is encouraged if it allows the offeror to more efficiently perform the numerous responsibilities required by this project. Offerors should describe the activities to be subcontracted, the method and level of integration between the prime and any proposed subcontractor(s), and the expected advantages of such an approach.

The **technical proposal may not exceed 40 pages. The appendix of the technical proposal may note exceed 250 pages. The technical proposal** should provide specific information addressing the elements listed in the Statement of Work and those specified below

(a) General Instructions:

(1) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's statement of work will not be eligible for award. The technical proposal should contain an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

(2) A detailed work plan must be submitted indicating how much each aspect of the statement of work is to be accomplished. This plan should be in as much detail as considered necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken.

(3) The technical proposal must include information on how the project is to be organized, staffed, and managed. This information should demonstrate your understanding of important events or tasks and their management. You must explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished.

(4) The technical proposal must list the names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. Their resumes should be included and should contain information on education, background, recent experience, and specific or technical accomplishments. The approximate percentage of

time each individual will be available for this project must be stated. The proposed staff hours of each individual should be allocated against each project task or subtask.

(5) The technical proposal must provide the general background, experience, and qualifications of the organization. Similar or related contracts, subcontracts, or grants should be included and contain the name of the customer, contract or grant number, dollar amount, time of performance, and the names and telephone numbers of the project officer and contracting officer/grants officer.

(6) The technical proposal must contain a discussion of present or proposed facilities and equipment that will be used in the performance of the contract.

(7) The technical proposal must not contain reference to cost; however, resource information, such as data concerning labor hours and categories, material, subcontracts, etc., must be contained in the technical proposal so that your understanding of the statement of work can be evaluated. See Attachment entitled "TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS (Sample)" in Section J. for recommended format.

The technical proposal must be prepared and submitted in the following format and, as a minimum, must include the following including the offerors demonstrated ability to meet the absolute criteria for eligibility outlined in Section M:

The technical proposal should be prepared and submitted, in a format to facilitate proposal evaluation, in accordance with the criteria specified in Section M. hereof, i.e., the proposal should contain a separate section addressing the offerors ability to meet the mandatory criteria for eligibility; a separate section addressing the offerors understanding and purpose of the problem; a separate section addressing the offerors understanding of the methodology and technical approach; a separate section addressing the offerors management plan and personnel; a separate section addressing the offerors facilities, and a separate section addressing the offerors past performance information.

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 22: **Proposal Cover Sheet,** is applicable to this solicitation and is included under Section J

ITEM 23: **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)],** is applicable to this solicitation.

ITEM 24: **Incremental Funding** is applicable to this solicitation.

ITEM 25: **Contractor shall provide a cost breakdown of all key elements in their proposal to meet milestone four (4) of the statement of work.** Contractor shall list cost plus fixed fee for these elements on the table in Section B.4.

SECTION M - EVALUATION FACTORS FOR AWARD

M.1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals as described in this section. The non-cost factors in order of importance are: technical, past performance, and Small Disadvantaged Business (SDB) participation. Offerors are advised that in the evaluation process, all evaluations other than cost or price, when combined, are approximately equal to cost or price. Technical activities must connect directly to costs in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the USG to consider award (s) to other than the lowest priced or highest technically rated Offeror. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government. For the purposes of this RFP, the U.S. is defined as the fifty states, the District of Columbia, and Puerto Rico.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

Contract(s) will be awarded to the Offeror(s) whose proposal is considered to be the most advantageous to the Government, cost and other factors (identified below) considered. Each Offeror must submit a proposal that separately addresses evaluation criteria specified below as they relate to the statement of work and delivery requirements.

M.2. Mandatory Criteria for Eligibility

The offeror shall provide an index, matrix, or dedicated section in the proposal that will direct reviewers to the specific area of the proposal that addresses particular mandatory qualifications.

1a. U.S. Manufacturing for Vaccine and Other Products Not Suitable for Stockpiling

Manufacturing facilities for antigen-sparing influenza vaccines or products that cannot be purchased in advance and stockpiled must be located in the U.S. to assure unencumbered access to the antigen-sparing vaccine or technology at the time of a pandemic, when products made outside of the U.S. may be retained in their country of manufacture despite pre-existing contractual agreements. The U.S. manufacturing facility for antigen-sparing products may be owned and operated by the pharmaceutical company or vaccine manufacturer acting as the Prime Contractor or the Prime Contractor's contract manufacturing organization acting as a subcontractor. To provide the U.S.-based facilities, the Offeror must provide a commitment to U.S.-based manufacturing following product licensure. The noted exception (in section M.1.1b) to this requirement is the manufacturing site of medical devices, which may be an FDA-licensed U.S. or foreign manufacturing facility provided that the product can be stockpiled, has a shelf life that is consistent with long term pandemic preparedness, and where production capacity is sufficient for rapid fulfillment of U.S. stockpile needs at the onset of an influenza pandemic to meet U.S. vaccine needs.

1b. Manufacturing Capacity and Commitment to Produce Products Suitable for Stockpiling

Written evidence of a firm commitment by the Offeror that the Offeror will initiate the establishment of the necessary facilities for the manufacturing of antigen sparing products that can be maintained long term in a stockpile with sufficient capacity such that at least 150 million units could be purchased by the USG for a stockpile within a 6 month period after U.S. licensure.

2. Agreements to Submit Product for Comparative Testing, Timeline and Intent for U.S. Product Licensure

Given the ongoing threat of an influenza pandemic, it is essential that efforts funded as a result of this requirement shall lead to U.S. licensure of an influenza vaccine and/or delivery system that can be used to protect the U.S. population in the event of an influenza pandemic. Therefore, Offerors must commit to the following to be considered for award:

(a) Agreement to submit the product to HHS for side-by-side comparison with other different antigen-sparing pandemic vaccine approaches for assessment of their relative capabilities in a standardized animal and/or clinical trial.

Therefore, Offerors must be willing to provide the NIH or HHS-designated Contractor upon request, with adequate remuneration, sufficient antigen-sparing vaccine or products and accompanying documentation to support implementation of such studies.

(b) Submission of an Investigational New Drug (IND) application to the FDA for initiation of Phase I clinical trials in the U.S. for safety and immunogenicity within 6 months of contract award.

(c) Provision of a clear and comprehensive plan and timeline for U.S. licensure of the influenza vaccine and/or delivery system presented in the proposal.

M.3. Technical Evaluation Criteria

Each set of proposals shall be evaluated according to the criteria and points as set forth below:

Evaluation Criteria	**Points**
1. Methodology and Approach	30
2. Comparative Advantage and Potential Limitations	15
3. Facilities	15
4. Personnel	15
5. Organizational Experience	15
6. Timeline to Licensure	10
TOTAL	100

1. Methodology and Approach

(a) The technical proposal should describe in detail, the product and/or method description, its mode of action, advantages and limitations, and previous supportive pre-clinical and clinical studies that document and define the magnitude of the antigen-sparing effect of the Offeror's vaccine, method, or product(s). Study populations, methods, vaccines used, comparison groups, and statistical analysis of studies defining antigen-sparing effects should be clearly defined.

(b) The technical proposal must describe in detail the antigen-sparing approach including all biological constituents, components, and products required to achieve the enhanced immunity and/or antigen-sparing effect. The Offeror must identify whether each biological constituent, component, and product is already licensed by the FDA or used in or with any FDA-licensed vaccine or biological product. For constituents, components, and products that are not licensed by the FDA, the Offeror should describe any regulatory barriers to licensure that have been identified by the FDA, other regulatory agencies, or the Offeror and clearly describe what studies, tests, or processes will be done or employed to address, mitigate, or eliminate these barriers.

(c) The technical proposal should identify the advantages and limitations of the proposed antigen-sparing strategy as compared to other potential approaches. Specifically, the Offeror should compare the magnitude of the enhanced immunity and/or antigen-sparing effects, potential barriers to licensure, the ability to use the strategies or products with pandemic influenza vaccines produced by different manufacturers globally, feasibilities to implement as part of a mass vaccination program in a pandemic response, and other factors that may differentiate the Offeror's strategy from other approaches. If limitations are identified, potential strategies to overcome the limitations should be described.

2. Comparative Advantage and Potential Limitations

(a) The technical proposal should provide a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget specifying activities to be supported by the government. The level of detail contained in the CWP and the corresponding Gantt chart should be sufficient to facilitate management and execution of the contract by the successful Offeror(s).

(b) The technical proposal should describe methods and results of all previous pre-clinical and clinical testing that has been completed by the Offeror or others, where possible, in the U.S. or internationally including description of test populations, vaccine used (formulation, dose, schedule, etc.), and results.

(c) The technical proposal should describe, in detail, the Offeror's work plan to complete all activities identified in the statement of work. Discuss phasing and integration of research and development activities and, as possible, include experimental design, including sample size and analytic strategy. Indicate anticipated difficulties in carrying out the research plan and potential approaches to overcome them. Decision trees for the critical pathway for product development should be provided for manufacturing, process development, product assay development, clinical evaluation, clinical assay development, master validation plan, and regulatory licensure plan.

(d) The technical proposal should describe the extent to which the Offeror has unencumbered access to intellectual property necessary to fulfill its obligations under the contract. The U.S. Government expects and intends to require that the Offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials. Accordingly, the U.S. Government requires written evidence of the extent to which the Offeror has secured access to such intellectual property, know-how and tangible materials to suitable adjuvant, immunostimulants, immune cytokines, vaccine administration, and/or medical device technology unencumbered by legal or patent constraint.

3. Facilities

(a) For products that cannot be stockpiled, the proposal should describe the Offeror's corporate strategy for producing the antigen-sparing vaccine or products at a qualified U.S.-based manufacturing facility capable of producing up to 150 million monovalent pandemic influenza vaccine doses or units of antigen-sparing product in six months. If appropriate, include a description of the proposed biocontainment level of the facility and its compliance with current WHO guidelines for pandemic influenza vaccine manufacturing. Identify potential barriers to implementation of the facility strategy and approaches to overcome those barriers.

(b) For products with long-term stability that are suitable for stockpiling as part of pandemic preparedness, the proposal should describe facilities to be used for development and manufacture of the products, including documentation of compliance with cGMP and suitability for FDA licensure. Facilities must be capable of producing up to 300 million units over a six month period that would be available for U.S. stockpile purchase. If needed, for example for a biological product, provide detailed data on product shelf-life and suitability for stockpiling. Identify potential barriers to implementation of the facility strategy and approaches to overcome those barriers.

4. Organizational Experience

The proposal should describe previous programs for vaccine, biological product, or device evaluation, licensure, and production to document organizational capabilities to complete proposed activities, achieve regulatory approvals, and successfully produce the antigen sparing-vaccine or products.

5. Personnel

(a) The technical proposal should provide the name of the Principal Investigator (PI)/Project Director responsible for the overall implementation of the contract, Co-investigators and key participants for technical aspects of the project. Describe the qualifications, experience, and accomplishments of the PI, Co-investigators, and key participants. Include, in an attachment, *curricula vitae* of supervisors and key technical personnel, and the approximate percentage of time each will be available for this program.

(c) The technical proposal should describe the experience and qualifications of other personnel who will be assigned to work on this program. Using organizational charts, show the composition of task or work groups by project area. Document the general qualifications of work groups and recent experience with similar programs.

(c) The technical proposal should list names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. Indicate the technical areas, character, and extent of subcontract or consultant activities and anticipated sources. For all proposed personnel who are not currently members of Offeror's staff, provide a letter of commitment or other evidence of availability. The letter of commitment must at a minimum include (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a consultant and (4) how rights to publication and patents will be handled.

6. Timeline to licensure

If the Contractor Work Plan (see milestone four (4) of the statement of work) does not extend to vaccine or product licensure and production, the proposal should provide a timeline that projects time to accomplishment of these activities.

M.4. Past Performance Information

1. Offerors shall submit the following informality as part of their business proposal for both the Offeror and proposed major subcontractors:

2. The Offeror shall provide a list of the last three (3) contracts completed during the past three years and all contracts awarded currently in process that are similar in nature to the solicitation work scope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts as required above for all key personnel:

a. Name of Contracting Organization

b. Contract Number

c. Total Contract Value

d. Description of Requirement

e. Contract Officer's name and telephone number

f. Program Manager's name and telephone number

3. Each Offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for both responsibility determinations and as an evaluation factor against which the Offerors relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The government is not required to contact all references provided by the Offeror, and references other than those identified by the Offeror may be contacted by the Government to obtain additional information that will be considered in the evaluation of the Offerors past performance.

4. An evaluation of Offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

5. The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the Offeror as it relates to all acquisition requirements, such as the Offeror's record of performing according to specifications, including standards of good workmanship; the Offeror's record of controlling and forecasting costs; the Offeror's adherence to contract schedules, including the administrative aspects of performance; the Offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the Offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be to the advantage nor disadvantage of the Offeror.

The following rating method shall be used in the evaluation of past performance information:

+2 Excellent - Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.

+1 Good - Based on the Offeror's performance record, little doubt exists that the Offeror will successfully perform the required effort. Sources of information state that the Offeror's performance was good, better than average, etc., and that they would do business with the Offeror again.

0 Average – Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is average or that favorable reports are offset by unfavorable reports.

-1 Marginal - Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information make unfavorable reports about the Offeror's performance and express concern about doing business with the Offeror again.

-2 Poor - Based on the Offeror's performance record, serious doubt exists that the Offeror will successfully perform the required effort. Sources of information consistently stated that the Offeror's performance was entirely unsatisfactory and that they would not do business with the Offeror again.

M. 5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the Offeror's SDB Participation targets will be used in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

Extent to which SDB concerns are specifically identified
Extent of commitment to use SDB concerns
Complexity and variety of the work SDB concerns are to perform
Realism of the proposal
Past performance of Offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
Extent of participation of SDB concerns in terms of the value of the total acquisition.

M. 6. STUDIES THAT INVOLVE HUMAN SUBJECTS

This research project involves human subjects. DHHS Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The DHHS will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

HUMAN SUBJECT EVALUATION

1. This research project may involve human subjects. DHHS Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by Institute that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health,; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.
Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

M.7. Animal Welfare

Offerors must submit a plan on how they will comply with all requirements concerning the use of animals for experimentation and be in accordance with any requirements specified and be in accordance of any requirements of the Office of Laboratory Animal Welfare: http://grants.nih.gov/grants/olaw/olaw.htm.

M.8. Relative Importance of Cost or Price and Other Evaluation Factors

All evaluation factors other than cost or price, when combined, are approximately equal to cost or price.